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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In application of: Richard E. Weller et al.

Application No. 10/784,147

Filed: February 19, 2004

Confirmation No. 5344

For: THERAPEUTIC AGENT CARRIER
COMPOSITIONS

Examiner: Not yet assigned

Art Unit: 1616

Attorney Reference No. 23-65308-01

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Attorney
for Applicant(s)

Kevin M. Hayes

Date Mailed December 23, 2004

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INFORMATION DISCLOSURE STATEMENT
FOR CONTINUING APPLICATIONS

Listed on the accompanying form PTO-1449 are several English-language and/or non-English-language documents (English translations are included for the non-English documents). Applicants respectfully request that such documents be listed as references cited on the issued patent.

Copies of United States patents and United States published patent applications do not have to be provided to the Patent Office (37 C.F.R. 1.98a)(2)(ii)). Copies of unpublished U.S. applications do not have to be provided, as long as the application is available on PAIR, as this requirement of 37 C.F.R. § 1.98(a)(2)(iii) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on October 19, 2004 (1287 OG 163). Applicants will provide copies of such patents or applications upon request.

The present application relies upon several earlier filings for an earlier filing date under 35 U.S.C. § 120, including, U.S. Patent Application No. 09/994,509, filed November 26, 2001, which is a continuation-in-part application of Application No. 09/853,507, filed May 9, 2001, which is a continuation of Application No. 09/058,712, filed April 10, 1998, now U.S. Patent No. 6,296,831, and Application No. 10/124,614, filed April 16, 2002, which is a continuation-in-part of Application No. 09/833,460, filed April 11, 2001, which application claims the benefit under 35 U.S.C. § 119(e) of provisional patent Application No. 60/236,926, filed September 28, 2000. Certain documents listed on the accompanying form PTO-1449 were disclosed to or cited by the Patent Office in the listed earlier U.S. applications.

Copies of the non-U.S. patent documents listed on the accompanying form PTO-1449 that were cited by applicants in the earlier listed applications need not be sent to the Patent Office pursuant to 37 C.F.R. § 1.98 (these are marked with "***" in the Cite No. column). However, applicants will furnish the Patent Office with such copies upon request.

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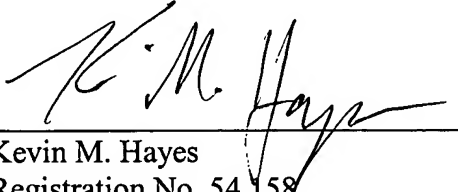
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Respectfully submitted,

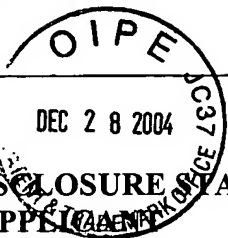
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**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

Attorney Docket Number	23-65308-01
Application Number	10/784,147
Filing Date	February 19, 2004
First Named Inventor	Weller
Art Unit	1616
Examiner Name	Not yet assigned

U.S. PATENT DOCUMENTS

NOTE: If this application was filed after June 30, 2003, copies of United States patents and United States published patent applications do not have to be provided to the Patent Office. This requirement of 37 C.F.R. § 1.98(a)(2)(i) has been waived by the United States Patent and Trademark Office pursuant to the Official Gazette Notice on August 5, 2003 (1276 OG 55).

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		3,866,050	02/11/75	Whitfield
		4,190,461	02/26/80	Hedger
		4,418,052	11/29/83	Wong
		4,438,253	03/20/84	Casey et al.
		4,510,924	04/16/85	Gray
		4,526,938	07/02/85	Churchill et al.
		4,754,745	07/05/88	Horowitz
		4,763,642	08/16/88	Horowitz
		4,946,686	08/07/90	McClelland et al.
		5,213,580	05/25/93	Slepian et al.
		5,227,969	07/13/93	Waggener et al.
		5,262,055	11/16/93	Bae et al.
		5,278,201	01/11/94	Dunn et al.
		5,322,499	06/21/94	Liprie
		5,424,288	06/13/95	Order

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Attorney Docket Number	23-65308-01
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		5,441,732	08/15/95	Hoeg et al.	
		5,449,513	09/12/95	Yokoyama et al.	
		5,462,990	10/31/95	Hubbell et al.	
		5,538,726	07/23/96	Order	
		5,561,698	10/01/96	Mick et al.	
		5,562,594	10/08/96	Weeks	
		5,575,815	11/19/96	Slepian et al.	
		5,631,337	05/20/97	Sassi et al.	
		5,634,946	06/03/97	Slepian	
		5,635,709	06/03/97	Sliski et al.	
		5,646,131	07/08/97	Badwan et al.	
		5,662,609	09/02/97	Slepian	
		5,674,287	10/07/97	Slepian et al.	
		5,702,717	12/30/97	Cha et al.	
		5,749,915	05/12/98	Slepian	
		5,749,922	05/12/98	Slepian et al.	
		5,762,903	06/09/98	Park et al.	
		5,792,742	08/11/98	Gold et al.	
		5,820,879	10/13/98	Fernandez et al.	
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		5,843,156	12/01/98	Slepian et al.	
		5,858,746	01/12/99	Hubbell et al.	
		5,942,209	08/24/99	Leavitt et al.	
		6,004,573	12/21/99	Rathi et al.	
		6,007,845	12/28/99	Domb et al.	
		6,060,582	05/09/00	Hubbell et al.	
		6,015,541	01/18/00	Greff et al.	
		6,083,524	07/04/00	Sawhney et al.	
		6,117,949	09/12/00	Rathi et al.	
		6,290,729	09/18/01	Slepian et al.	
		6,296,831	10/02/01	Weller et al.	
		6,352,682	03/05/02	Leavitt et al.	
		6,443,941	09/03/02	Slepian et al.	
		US2001/0024636 A1	09/27/2001	Weller et al.	
		US2001/0034050 A1	10/25/01	Chilkoti	
		US2002/0032309 A1	03/14/02	Deming et al.	
		US2002/0168319A1	11/14/02	Filler et al.	
		US2003/0035838	02/20/03	Prokop	

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FOREIGN PATENT DOCUMENTS					
Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		PCT	WO 91/01884	02/21/91	Redford et al.
		PCT	WO 91/04104	04/04/91	Beatty
	**	PCT	WO 95/00162	01/05/95	Mensi-Fattohi et al.
	**	PCT	WO 95/24430	09/14/95	Hoffman et al.
	**	PCT	WO 96/03112	02/08/96	Filler et al.
		PCT	WO 96/10376	04/11/96	Rincoe
	**	PCT	WO 97/09068	03/13/97	Hoffman et al.
	**	PCT	WO 97/33628	09/18/97	Leavitt et al.
	**	PCT	WO 98/55147	12/10/98	Gutowska
	**	PCT	WO 99/07343	02/18/99	Jeong et al.
	**	PCT	WO 99/18142	04/15/99	Rathi et al.
	**	PCT	WO 00/56774	09/28/00	Chilkoti
	**	PCT	WO 00/21574	04/20/00	Kinstler et al.
	**	PCT	WO 01/67104	09/13/01	Chilkoti et al.
	**	PCT	WO 02/26215	04/04/02	Jeong et al.
		EP	0534015 A1	03/31/93	Mikami et al.
	**	EP	0730871 A1	09/11/96	Park et al.

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Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
	PTO	Aime et al., "Synthesis, Characterization, and 1/T ₁ NMRD Profiles of Gadolinium(III) Complexes of Monoamide Derivatives of DOTA-Like Ligands. X-Ray Structure of the 10-[2-[[2-Hydroxy-1-(hydroxymethyl)ethyl]amino]-1-[(phenylmethoxy)methyl]-2-oxo-ethyl]-1,4,7,10-tetraazacyclododecane-1,4,7-triacetic Acid-Gadolinium(III) Complex," <i>Inorg. Chem.</i> 31:2422-2428 (1992).
	**	Alexandridis et al., "Micellization of Poly(ethylene oxide)-Poly(propylene oxide)-Poly(ethylene oxide) Triblock Copolymers in Aqueous Solutions. Thermodynamics of Copolymer Association," <i>Macromolecules</i> 27:2414-2425 (1994).
	PTO	Amiya et al., "Phase Transitions in Cross-Linked Gels of Natural Polymers," <i>Macromolecules</i> 20:1162-1164 (1987).
	PTO	Bae et al., "Temperature Dependence of Swelling of Crosslinked Poly(N, N'-Alkyl Substituted Acrylamides) in Water," <i>Journal of Polymer Science: Part B: Polymer Physics</i> 28:923-936 (1990).
	**	Behravesh et al., "Synthesis and Characterization of Triblock Copolymers of Methoxy Poly(ethylene glycol) and Poly(propylene fumarate)," <i>Biomacromolecules</i> , pp. A-F (2001).
	**	Bellare et al., "Controlled Environment Vitrification System: An Improved Sample Preparation Technique," <i>Journal of Electron Microscopy Technique</i> , 10:87-111 (1988).
	**	Betre et al., "Injectable Elastin-Like Polypeptide for Cartilage Repair," 47 th Annual Meeting, Orthopaedic Research Society, p. 601 (February 25-28, 2001).
	**	Brown et al., "Micelle and Gel Formation in a Poly(ethylene oxide)/Poly(propylene oxide)/Poly(ethylene oxide) Triblock Copolymer in Water Solution. Dynamic and Static Light Scattering and Oscillatory Shear Measurements," <i>J. Phys. Chem.</i> 95:1850-1858 (1991).
	**	Cau et al., "H NMR Relaxation Studies of the Micellization of a Poly(ethylene oxide)-Poly(propylene oxide)-Poly(ethylene oxide) Triblock Copolymer in Aqueous Solution," <i>Macromolecules</i> 29:170-178 (1996).
	**	Chen et al., "Graft Copolymers That Exhibit Temperature-Induced Phase Transitions Over a Wide Range of pH," <i>Nature</i> 373:49-52 (1995).
	**	Chilkoti et al., "A Genetically Engineered Polypeptide Carrier for Thermal Targeting of Therapeutics," 2pp. (2001).
	**	Deming, "Facile Synthesis of Block Copolypeptides of Defined Architecture," <i>Nature</i> , 390:386-390 (November 1997).

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<p>* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

	**	Deng et al., "Thermodynamics of Micellisation and Gelation of Oxyethylene/Oxypropylene Diblock Copolymers in Aqueous Solution Studied by Light Scattering and Differential Scanning Calorimetry," <i>J. Chem. Soc. Faraday Trans.</i> 88:1441-1446 (1992).
	**	Discher et al., "Polymersomes: Tough Vesicles Made from Diblock Copolymers," <i>Science</i> pp. 1-9 (1999).
	**	Fairchild et al., "Samarium-145 and its Use as a Radiation Source," Statutory Invention Registration, H699, 7 pp. (9/5/89).
	**	Feil et al., "Effect of Comonomer Hydrophilicity and Ionization on the Lower Critical Solution Temperature of <i>N</i> -Isopropylacrylamide Copolymers," <i>Macromolecules</i> 26:2496-2500 (1993).
	**	Gutowska et al., "Injectable Gels for Tissue Engineering," pp. 1-26 (2000).
	**	Gutowska et al., "Thermosensitive Polymers for Drug Delivery," pp. 115-116 (1996).
	**	Hill-West et al., "Inhibition of Thrombosis and Intimal Thickening by <i>in situ</i> Photopolymerization of Thin Hydrogel Barriers," <i>Proc. Natl. Acad. Sci. USA</i> 91:5967-5671 (1994).
	**	Hoffman et al., "Conjugates of Stimuli-Responsive Polymers and Biomolecules: Random and Site-Specific Conjugates of Temperature-Sensitive Polymers and Proteins," <i>Macromol. Symp.</i> 118:553-563 (1997).
	PTO	Hoffman, A.S., "Environmentally Sensitive Polymers and Hydrogels," <i>MRS Bulletin</i> , pp. 42-46 (1991).
	**	Israelachvili, J.N., "Intermolecular and Surface Forces," pp. 102-106, 207-208 (1985).
	**	Jeong et al., "Biodegradable Block Copolymers as Injectable Drug-Delivery Systems," <i>Nature</i> 388:860-862 (1997).
	**	Jeong et al., "Biodegradable Thermoreversible Gelling Polymer with a Maximum Modulus at Body Temperature," 14 pp. (2000).
	**	Jeong et al., "Biodegradable Thermosensitive Micelles of PEG-PLGA-PEG Triblock Copolymers," <i>Colloids and Surfaces B: Biointerfaces</i> 16:185-193 (1999).
	**	Jeong et al., "Drug Release from Biodegradable Injectable Thermosensitive Hydrogel of PEG-PLGA-PEG Triblock Copolymers," <i>Journal of Controlled Release</i> 63:155-163 (2000).
	**	Jeong et al., " <i>In situ</i> Gelation of PEG-PLGA-PEG Triblock Copolymer Aqueous Solutions and Degradation Thereof," pp. 171-177 (2000).
	**	Jeong et al., "New Biodegradable Polymers for Injectable Drug Delivery Systems," <i>Journal of Controlled Release</i> 62:109-114 (1999).

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	**	Jeong et al., "Reverse Thermogelling Biodegradable Polymers: PEG-g-PLGA," 7 pp.
	**	Jeong et al., "Thermogelling Biodegradable Polymers with Hydrophilic Backbones: PEG-g-PLGA," <i>Macromolecules</i> , pp. A-F (2000).
	**	Jeong et al., "Thermoreversible Gelation of PEG-PLGA-PEG Triblock Copolymer Aqueous Solutions," <i>Macromolecules</i> 32:7064-7069 (1999).
	**	Jeong et al., "Thermoreversible Gelation of Poly(Ethylene Oxide) Biodegradable Polyester Block Copolymers," pp. 751-760 (1998).
	**	Jhon et al., "Water and Hydrogels," <i>J. Biomed. Mater. Res.</i> 7:509-522 (1973).
	**	Johnston et al., "Sustained Delivery of Interleukin-2 From a Polymer 407 Gel Matrix Following Intraperitoneal Injection of Mice," <i>Pharmaceutical Research</i> 9:425-434 (1992).
	PTO	Lewis, Sr., R.J., "Hawley's Condensed Chemical Dictionary," pp. 28, 124-125, 256, 785 (1993). (Copy made from PTO copy)
	**	Malmsten et al., "Self-Assembly in Aqueous Block Copolymer Solutions," <i>Macromolecules</i> 25:5440-5445 (1992).
	**	Meyer et al., "Drug Targeting Using Thermally Responsive Polymers and Local Hyperthermia," <i>Journal of Controlled Release</i> 74:213-224 (2001).
	PTO	Moi et al., "Copper Chelates as Probes of Biological Systems: Stable Copper Complexes with a Macrocyclic Bifunctional Chelating Agent," <i>Analytical Biochemistry</i> 148:249-253 (1985).
	**	Moiseev, L., "Temperature-Dependent Properties of Elastin-Like Polypeptides (ELP)," http://www.bu.edu/mcbb/calendar_of_events/abstracts/moiseev_abstract.htm (January 21, 2000).
	**	Nath et al., "Interfacial Phase Transition of an Environmentally Responsive Elastin Biopolymer Adsorbed on Functionalized Gold Nanoparticles Studied by Colloidal Surface Plasmon Resonance," <i>J. Am. Chem. Soc.</i> 123:8197-8202 (2001).
	**	Ning et al., "Intratumoral Radioimmunotherapy of a Human Colon Cancer Xenograft Using a Sustained-Release Gel," <i>Radiotherapy and Oncology</i> 39:179-189 (1996).
	**	Odian, G., "Principles of Polymerization," pp. 512-515 (1981).
	**	Order et al., "Preliminary Experience of Infusional Brachytherapy Using Colloidal ³² P," <i>Annals Academy of Medicine</i> 25:347-351 (1996).
	**	Osada et al., "Intelligent Gels," <i>Scientific American</i> , pp. 82-87 (1993).
	PTO	Peppas, N.A., "Hydrogels in Medicine and Pharmacy," Volume II Polymers, Chapter 5, pp. 115-160 (1987).

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	**	Piervincenzi, R.T., Article – “Research Interests: Exploiting Protein Engineering to Develop Novel Molecular Tools for Improving Applications in the Fields of Drug Delivery and Biosensor Development,” 3 pp. (1998).
	PTO	Priest et al., “Lower Critical Solution Temperatures of Aqueous Copolymers of <i>N</i> -Isopropylacrylamide and Other <i>N</i> -Substituted Acrylamides,” <i>Reversible Polymeric Gels and Related Systems</i> , Chapter 18, pp. 255-264 (1987).
	**	Raucher et al., “Enhanced Uptake of a Thermally Responsive Polypeptide by Tumor Cells in Response to its Hyperthermia-Mediated Phase Transition,” <i>Cancer Research</i> 61:7163-7170 (2001).
	PTO	Renard et al., “Gelation of Globular Proteins: Effect of pH and Ionic Strength on the Critical Concentration for Gel Formation. A Simple Model and its Application to β -Lactoglobulin Heat-Induced Gelation,” <i>Int. J. Biol. Macromol.</i> 14:287-291 (1992).
	**	Rosiak et al., “Hydrogels for Biomedical Purposes,” <i>Nucl. Instr. and Meth. in Phys. Res. B</i> 105:335-339 (1995).
	PTO	Sherry et al., “Synthesis and Characterization of the Gadolinium (3+) Complex of DOTA-Propylamide: A Model DOTA-Protein Conjugate,” <i>Inorg. Chem.</i> 28:620-622 (1989).
	**	Stile et al., “Synthesis and Characterization of Injectable Poly(<i>N</i> -isopropylacrylamide)-Based Hydrogels that Support Tissue Formation <i>in Vitro</i> ,” <i>Macromolecules</i> 32:7370-7379 (1999).
	**	Tanodekaew et al., “Gelation of Aqueous Solutions of Diblock Copolymers of Ethylene Oxide and D,L -Lactide,” <i>Macromol. Chem. Phys.</i> 198:3385-3395 (1997).
	**	Thomas et al., “Tuning the Response of a pH-Sensitive Membrane Switch,” <i>J. Am. Chem. Soc.</i> 117:2949-2950 (1995).
	**	Wanka et al., “The Aggregation Behavior of Poly-(oxyethylene)-Poly-(oxypropylene)-Poly-(oxyethylene)-Block-Copolymers in Aqueous Solution,” <i>Colloid Polym Sci</i> 268:101-117 (1990).
	**	Won et al., “Giant Wormlike Rubber Micelles,” <i>Science</i> , pp. 960-963 (1999).
	**	Wout et al., “Poloxamer 407-Mediated Changes in Plasma Cholesterol and Triglycerides Following Intraperitoneal Injection to Rats,” <i>Journal of Parenteral Science & Technology</i> 46:192-200 (1992).
	**	Yan et al., “Polymer Communications,” <i>Polymer</i> , 36:887-889 (1995).
	**	Yang et al., “Effect of Block Structure on the Micellization and Gelation of Aqueous Solutions of Copolymers of Ethylene Oxide and Butylene Oxide,” <i>Macromolecules</i> 27:2371-2379 (1994).

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	**	Yu et al., "Micellisation and Gelation of Triblock Copoly(oxyethylene/oxypropylene/oxyethylene), F127," <i>J. Chem. Soc. Faraday Trans.</i> 88:2537-2544 (1992).
	**	Zhou et al., "Light-Scattering Study on the Association Behavior of Triblock Polymers of Ethylene Oxide and Propylene Oxide in Aqueous Solution," <i>Journal of Colloid and Interface Science</i> 126:171-180 (1988).
	**	"Genetically Engineered Biomolecules May Help Cancer Treatment Delivery," http://www.dukenews.duke.edu/Daily00-01/chil.htm (March 9, 2001).

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